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Award Number: W81XWH-11-2-0157

TITLE: Burn Resuscitation Decision Support System (BRDSS)

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CONTRACTING ORGANIZATION: Arcos, Inc., Houston, TX 77018

REPORT DATE: November 2014

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
1November2014	Final	20-Jun-2011 to 19-Aug-2014

4. TITLE AND SUBTITLE
Burn Resuscitation Decision Support System (BRDSS)

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-11-2-0157

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Arcos, Inc.
Houston, TX 77002-8646

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The Burn Resuscitation Decision Support System (BRDSS) is a medical device designed to guide and optimize fluid resuscitation of severely burned patients. The goal of this cooperative agreement was to develop a mobile device that is safe and effective for burn care in the deployed and en route care settings. We developed a prototype system for clinical evaluation, down selected to the most preferred tablet system and worked extensively with US Army Institute of Surgical Research (USAISR) to improve the design of the device. We applied for and obtained FDA regulatory clearance after additional human factors validation and other testing. We worked with USAARL to obtain Aeromedical Certification. The device is now in Full Rate Production and is being used in military and civilian burn care hospitals.

15. SUBJECT TERMS
Burn resuscitation, decision support, fluid resuscitation, acute burn care

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	18	19b. TELEPHONE NUMBER *(include area code)*

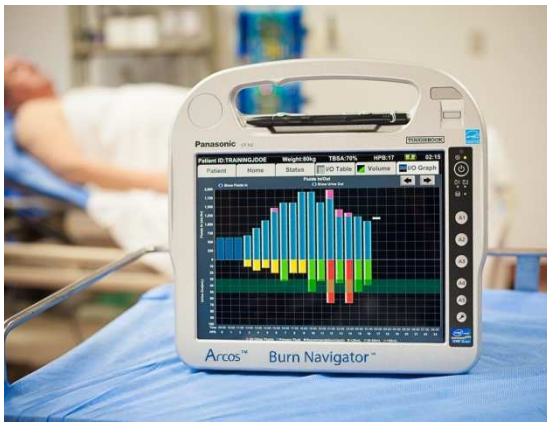
Burn Resuscitation Decision Support System (BRDSS)

Final Report

Table of Contents

I. Introduction

The Burn Resuscitation Decision Support System (BRDSS) is medical device software designed to guide and optimize fluid resuscitation of severely burned patients. The goal of this cooperative agreement was to package the software into a mobile device (the *BRDSS-M*, trade name *Burn Navigator*™) with substantial input from caregivers at the USAISR and the IPT, in order to have a safe and effective device for burn care in the deployed and en route care settings.



Burn Navigator™ final device

II. Body

A. Military Significance

Historically, 10% of all casualties during a military conflict involve burns. Of these, nearly 20% are categorized as severe or involving greater than 20% total body surface area (TBSA) and require significant intravenous resuscitation.[1,2] Between January 2003 and January 2006, 36% of combat casualties with >30% TBSA burns developed abdominal compartment syndrome (ACS) and perished.[2] Between January 2006 and June 2007, after the implementation of new procedures and burn flow sheets, incidence of ACS and mortality for large combat burn wounds dropped to 18%[2].

The goal of the BRDSS device (Burn Navigator™) is to provide model-based and individual patient trend-based fluid recommendations for treating combat casualties in order to reduce the incidence of ACS to 0%, minimize other complications resulting from over- and under-resuscitation and improve outcomes of wounded warriors. The BRDSS could be used on nearly all soldiers with serious burns requiring fluid resuscitation, starting at Level II / III and being used through Level V in the En Route Care System.

B. Statement of Work

The Statement of Work describes the project:

The Burn Resuscitation Decision Support System (BRDSS) Tablet project will be broken into four major phases. Throughout the project Arcos will have several meetings with the Decision Support Integrated Product Team (IPT), chaired by Mr. Scott Brady and LTC Serio-Melvin, MS, RN, and the designated U.S. Army Institute of Surgical Research (USAISR) clinical team.

Phase 1 System Requirements and Software Development

Arcos will draft a design plan for IPT or designee review to formalize the device design requirements. Upon design plan approval, Arcos will begin developing the

software to the Food and Drug Administration's (FDA's) design controls and creating the design history files. Arcos will present the core software on four (4) tablet hardware candidates to IPT or clinical group for user evaluation. The IPT or clinical group will provide feedback on the features, graphical user interface (GUI), and other design aspects. They will also select up to three (3) tablet hardware finalists in order of preference. Arcos will develop for each finalist a Special Medical Emergency Evacuation Device (SMEED) bracket and other test platform aspects needed for airworthiness testing. The hardware finalists will be sent to U.S. Army Aeromedical Research Laboratory (USAARL) for critical airworthiness testing.

Phase 2 Refinement, Verification and Validation

Arcos will refine the software based on IPT feedback. Arcos will incorporate robustness improvements, such as data error checking, and begin software unit verification, system level software and hardware verification, and thorough use testing. The final hardware will be chosen based on USAARL critical airworthiness testing results and IPT preference. Arcos will provide three (3) units of the final tablet with software for a second round of user evaluation. One unit of the final tablet will be sent to USAARL for secondary airworthiness testing and another unit will be sent for other electrical, safety, and performance testing as needed. Arcos will develop the attachment mechanism for bed, litter, or SMEED.

Phase 3 Packaging, Labeling, Certifications and Regulatory Preparations

Arcos will develop the device packaging and shipping materials and will ensure completion of all safety, effectiveness, performance, shipping, and environmental test certifications. Arcos will write the FDA 510(k) regulatory clearance application, including predicate device analysis, safety and effectiveness results, risk management, and draft labeling. The IPT will validate the pre-release device to ensure it meets all clinical needs and other Army requirements.

Phase 4 Complete Clinical Studies (if needed) and Obtain Regulatory Clearance

The FDA may require clinical studies to demonstrate safety and effectiveness of the BRDSS Tablet. Arcos will work with the Brooke Army Medical Center (BAMC) and U.S. Army Institute of Surgical Research (USAISR) for clinical studies to be performed on their premises. Arcos will submit the 510(k) application along with any new clinical study results to FDA. Arcos will finalize the user manual, labeling, serviceability plan and a set of PowerPoint slides for product training. The IPT or designated clinical group will assess the training

materials and all labeling for adequacy. Arcos will receive 510(k) clearance on the BRDSS Tablet.

C. Accomplishments toward Statement of Work

Phase 1 – System Requirements and Software Development

We held several meetings with the U.S. Army Institute of Surgical Research (ISR) clinical group and the Integrated Product Team (IPT) group regarding product requirements, including many functional requirements, SMEED attachments, airworthiness testing, software upgradability, maintenance, and other support needs. Based on these meetings, we completed the User Needs document.

Based on the User Needs document, we developed System Requirements, Software Requirements and Hardware Requirements. The software team determined the best software tools for displaying charts and graphs, the software architecture and communication protocol type (TCP).

With aid from a very experienced regulatory affairs consultant, we decided that an IDE (and thus a pre-IDE meeting with FDA) was not needed. We anticipated that referencing the clinical data from ISR's current version of the software and our bench testing of the BRDSS tablet will suffice for an FDA 510(k) clearance.

We realized early in the project that USAARL airworthiness testing would be the time limiting factor in completing the BRDSS project, so steps leading to USAARL testing took priority. The most important step preceding USAARL testing was choosing the hardware tablet candidates for BRDSS.

We created sample screens with basic functionality to help determine the appropriate software development tools and to allow users to perform tablet evaluations in the context of the rudimentary software. We screened dozens of tablets and selected four tablet candidates for BRDSS.

We created a 'wizard' based walk-through for starting a new patient and another wizard for fluid updates. A very significant amount of time was spent on content position, size, and interface continuity so that a new user can very quickly and easily understand what major information is being displayed and what questions need to be answered in every aspect of the software.

Most of the user evaluation work was facilitated by Mrs. Serio-Melvin, which ensured independent evaluations and feedback on the tablets. There seemed to be a broad consensus on which two tablets (the Panasonic H2 Toughbook® and the CF-19 Toughbook ®) were best suited for the BRDSS software across evaluators, even those with different care backgrounds.

The system manager allows the tablet to launch directly into the BRDSS software, without the normal Windows® interface. The system manager also allows software upgrades, battery status on the BRDSS software, and will shut down the tablet when the user presses "Shutdown BRDSS" in the software. Unfortunately, the system manager was not included in the Phase 1

software for user evaluations, which resulted in incomplete shutdown of Windows, batteries draining each night, and start-up problems during the next day of user evaluations. This was an oversight on our part and caused ISR, particularly Mrs. Serio-Melvin, consternation. The system manager was soon thereafter implemented in the tablets.

After the top two tablets were chosen, we sent the tablets to Impact Instrumentation, Inc., a sub-contractor on this project, to develop the SMEED brackets for the tablets. This step was re-ordered from our original plan, because Impact was planning to do vibration testing (as part of airworthiness testing), and users would not have been able to evaluate tablets that were vibrated until point of failure. We also heard from USAARL that they greatly preferred testing only two tablets simultaneously, rather than three. So we designed brackets for only the top two tablet candidates.

The decision to develop two brackets for two tablet candidates and to test two different tablets simultaneously was wise in retrospect. The airworthiness testing process took many months, so if only one tablet was tested and failed, then it would take most of a year to redo the tests with a second tablet. Of the two tablets, it turns out that the tablet we thought might fail airworthiness testing (H2 tablet) passed, whereas the more rugged looking tablet (CF-19) that we thought would pass airworthiness actually failed. It seems the extra weight of the CF-19 contributed to more of a whipping effect and, thus, it suffered greater forces on the test bed.

Airworthiness certification was obtained Aug 2013.

Phase 2 – Refinement, Verification and Validation

We held an all day, in-depth review of the software at ISR on 19 Dec 2011. By the end of that day, we finalized all the major software features and functionality requirements, including the wizards and unexpected technical challenges. One particular challenge was how to handle changing time zones during hand-offs in the en route care system which kept the fluid in & out record, as well as the number of minutes until the next fluid update, consistent when changing time zones.

Based on user feedback, we produced over 150 pages of product, hardware and especially requirements for the device. We also submitted over 200 pages of software verification test results to the FDA in the 510(k) application.

One new feature was developed in this phase that wasn't originally anticipated in the final device: Training Mode. We expected users would be trained classroom-style at ISR before deployment, but discovered that the deployment process does not allow centralized classroom training. Furthermore, we recognize that the most effective way to learn a new device is hands-on familiarization. When the BRDSS is used on patients as a released medical device, fluid updates should only happen once an hour (at the top of the hour). But forcing a user who is only trying to become familiar with the equipment to wait an hour between each fluid update would be very frustrating and impractical for learning purposes. With Maria Serio-Melvin's strong recommendation, we added a Training Mode into the final medical device. This training mode allows the user to accelerate the clock in the device when the patient ID starts with "training". The device will function normally when the patient ID begins otherwise. Handling time issues, resetting the clock, and separating training files from real patient files were a few of the several

design considerations that went into creating this new feature. We feel we achieved an elegant hands-on solution for familiarization that won't impact patient safety or data.

Clinical validation was done in two parts: ISR evaluations with questionnaires and AMEDD field testing. At ISR, 10 RNs and 2 MDs evaluated the BRDSS release candidates and answered seven evaluation questions. Of the seven questions, six had 80% - 100% favorable response. Only the transfer data process received mixed results. AMEDD's evaluation was conducted in May 2012. AMEDD's report was issued 11 July 2012.

The SMEED attachment brackets also underwent refinement based on ISR user feedback. Evaluators included people with Burn Flight Team experience. Several bracket design changes were requested and implemented.

The 510(k) application submitted to FDA in May 2012 included verification records and validation reports. However, FDA requested a human factors validation study to ensure the device was safe and usable as designed. *We found that three aspects of the software needed to be changed, so we made those changes, verified those changes, and conducted a follow-on human factors validation study to ensure that those changes were sufficient.*

Significantly more time and energy was given to the human factors validation studies than expected. This undertaking included significant time from Maria Serio-Melvin, MS, RN, at USAISR, as well as Ada Garcia, both study coordinators for the human factors validation studies.

The human factors validation study is described in "Conducting a FDA Human Factors Study on a Burn Resuscitation Decision Support System"[3], by Maria L. Serio-Melvin, RN, MSN, Chris Meador, MBA, and Ada Garcia, RN, a poster presented at MHSRS 2013. (See Appendix B.)

FDA accepted the final human factors report.

We also worked with engineers at USAARL for aeromedical certification. On 08-Aug-2013, Arcos' Burn Navigator obtained Aeromedical Certification for H-60 Blackhawk helicopters from the U.S. Army, based on airworthiness testing performed by the U.S. Army Aeromedical Research Laboratory (USAARL).

This certification means the Burn Navigator is approved for patient care use during flight on these aircraft and allows the Burn Navigator to be used in military en-route care, provided that aircrew and medical personnel are familiar with the instructions and guidance in the certification documents.

Helicopter certification requires one of the most rigorous sets of tests, including hard acceleration in multiple directions, lifetime vibration testing and rigorous electromagnetic compatibility testing.

Obtaining aeromedical certification on 8 Aug 2013 completed this phase of the Statement of Work.

Phase 3 – Packaging, Labeling, Certifications and Regulatory Preparations

Device packaging and shipping materials were chosen in the first year of the study and provided to USAISR with the BRDSS prototypes. Environmental test certifications (primarily: EMC and RFID testing) was completed in Q1 2013.

Labeling includes labeling directly on the device as well as the User's Manual. All copies of the labeling were included in the 510(k) application. The User's Manual was also subject to human factors validation study feedback from 15 participants in Dec 2012. We made improvements to the User's Manual based on that feedback. Those improvements were evaluated in the Feb 2013 follow-on human factors validation study.

The initial 626-page 510(k) regulatory application was completed and sent to FDA in May 2012.

Phase 4 – Complete Clinical Studies (if needed) and Obtain Regulatory Clearance

FDA reviewed the 510(k) application in summer 2012. The Agency requested data demonstrating that the device was effective in the patient population. USAISR provided data collected from 207 patients resuscitated with aid of the BRDSS algorithms. FDA accepted this data and did not ask for additional clinical studies.

We obtained FDA 510(k) clearance in Apr 2013. (See Appendix A, 510(k) certification letter.) The device training slides were not part of the 510(k), but were part of the human factors validation study and part of the roll-out plan. The training slides were completed in Dec 2012 and are updated periodically to keep up with software versions and to improve the training session.

We also conducted hardware based testing, such as electromagnetic compatibility (EMC) and radio-frequency identification (RFID) compatibility testing. These reports, along with the human factors validation report, were submitted to FDA in Q1, 2013.

Arcos asked for a no cost extension through Aug 2014. During this time we continued to refine the Burn Navigator software based on use experience at ISR, including fixing a few minor bugs in the software. We also continued to improve the training / familiarization materials.

During the last year of the project, Arcos also released the Burn Navigator Data Tool. The Data Tool allows users and researchers to transform the encrypted patient file into a PDF report and a Microsoft Excel CSV file. The PDF report is used for after action reviews, quality improvement and training. The CSV file contains numerical hourly data and other information; the CSV data can be opened in Excel for graphing and data analysis or uploaded to another data repository.

We expect that easy numerical exportation of these data will aid researchers in improving fluid resuscitation and burn care in the future.

D. Future Work

Future work in three areas could improve effectiveness of this technology.

Field Feedback. The BRDSS / Burn Navigator™ devices are now in Full Rate Production. As the devices are deployed in the field and used, feedback from field users could lead to improved design of the technology. Developing an interactive, guided practice session that is accessed online or contained in the device itself could also make equipment familiarization easier for field users.

Closed loop system. While this technology represents a major step forward for burn resuscitation and is being adopted by leading civilian burn centers, it still requires several manual steps prone to human error: urine output data entry and adjusting infusion pump rates. A closed-loop, or even an open-loop system, could integrate the urine output monitor and infusion pump and free up the caregiver from manual data entry tasks to focusing on clinical care.

Cloud-based system. The Burn Navigator™ software can also be stored online and run through 'apps' on users' smartphones or personal tablets. This configuration would reduce 'one more piece of equipment' used during transport, but would require a significant amount of development, since the software will have to be designed to fit with a wide variety of tablets (graphical user interface redesign, dynamic sizing, etc.) rather than the single H2 Toughbook. FDA clearance will also be needed on a cloud-based version.

E. Deliverables Completed

Deliverables and status:

1. Four (4) different hardware tablet candidates with core software for Phase 1 User Evaluations. ***Done.*** *USAISR caregivers provided feedback in the first year of the project.*
2. Six (6) units of the final hardware tablet with complete software for Phase 2 User Evaluations. ***Done.*** *Phase 2 User Evaluations were conducted at USAISR, also with AMEDD; additionally we did two Human Factors validation studies.*
3. A pre-release product incorporating one unit of the above final hardware tablets, the latest software, the attachment mechanism (for patient bed, litter, or SMEED), draft user manual, and training materials. ***Done.*** *We completed the attachment mechanisms; USAISR has two attachment mechanism units. A draft user manual and training slides were completed in the first year of the project; both were refined during the human factors validation studies. USAISR has at least one copy of the user's manual and the training slides.*

4. A Confidential electronic copy (.PDF) of the 510(k) application submitted to FDA. ***Done.*** *Completed in the first year of the project, May 2012, shortly after the application was submitted to the FDA. The 510(k) application was provided to ISR and the IPT co-chairs.*
5. A Confidential, Proprietary Technical Data Package (.PDF), which will include: System Requirements, Software Requirements Specification, Hardware Requirements Specification, Attachment Mechanism Design, Risk Management Summary, and Program Executable File (.EXE) at time of 510(k) submission. ***Done.*** *The technical data package was also provided to USAISR at the time of 510(k) submission.*
6. A PDF copy of the FDA 510(k) clearance letter. ***Done.*** *A copy of this letter was forwarded to USAISR and MRMC in April 2013. It is also included as Appendix A below.*

All major deliverables were completed.

III. Key Research Accomplishments

Development accomplishments include:

- **Developed a user-friendly, burn resuscitation decision support medical device**
- **Passed human factors validation studies**
- **Obtained FDA 510(k) clearance!**
- **Milestone C decision!**
- **Blackhawk aeromedical certification**

IV. Reportable Outcomes

Reportable outcomes include:

- **FDA clearance of a new medical device**[Appendix A]
- **FDA human factors study poster**[3, Appendix B]
- **Milestone C decision**
- **Blackhawk aeromedical certification**
- **Commercialization partner (Arcos) in place**
- **Manufacturing facility (Arcos) registered with FDA**
- **Entered Full Rate Production to meet military equipment needs**
- **Adoption of technology in leading civilian Burn ICUs**

V. Conclusion

This cooperative agreement has successfully resulted in bringing a new medical device to market for military and civilian use. This device utilizes sophisticated algorithms developed by burn care experts to guide and optimize fluid resuscitation for severely burned patients. The device has received 510(k) clearance, aeromedical certification, Milestone C decision and is now in Full Rate Production. The device is now commercially available for deployment and en route care and is now being used in civilian Burn ICUs.

VI. References

1. Chung KK, Blackbourne LH, Wolf SE, et al. Evolution of burn resuscitation in Operation Iraqi Freedom. J Burn Care Res. 2006; 27:606–611.
2. Ennis JL, Chung KK, Renz EM, et al. Joint Theater Trauma System Implementation of Burn Resuscitation Guidelines Improves Outcomes in Severely Burned Military Casualties. J Trauma. 2008; 64:S146-S152.
3. Serio-Melvin, ML et al, "Conducting a FDA Human Factors Study on a Burn Resuscitation Decision Support System", Poster, MHSRS 2013.

VII. Appendices

A. Appendix A – FDA 510(k) Clearance Letter

Arcos

K121659
p 1/2

Burn Resuscitation Decision Support System
510(k) Summary

APR 1 8 2013

Submitted by: Arcos, Inc.
866 W. 41st St.
Houston, TX 77018

Contact: Chris Meador
713-397-3030

Date Prepared: May 25, 2012

Product Trade Name: Burn Resuscitation Decision Support System (BRDSS)

Common Name: Drug Calculator

Classification: Class II

Classification Name: 21 CFR 868.1890, *Predictive Pulmonary-function value calculator*. Product Code: PDT

Predicate Device: K011571, TRxF Intelligent Dosing System™

Device Description: The BRDSS is a fluid calculator for use in the care of seriously burned patients. It is used to calculate the next dose of fluid for patients.

Indications For Use

The Burn Resuscitation Decision Support System (BRDSS) is indicated for use in the care of adult patients with 20% or more Total Body Surface Area (TBSA) burned as a fluid resuscitation calculator for hourly fluid recommendations. The BRDSS is intended to be initiated within 24 hours of the burn.

Substantial Equivalence

A. Predicate Device Comparison

	Predicate Device K011571 TRxF Intelligent Dosing System™	Applicant Burn Resuscitation Decision Support System (BRDSS)
Device Description	The IDS™ is a next-dose calculator for any drug that can be used by physicians to calculate the next dose for patients.	The BRDSS is a fluid calculator for use in the care of seriously burned patients. It is used to calculate the next dose of fluid for patients.

Intended Use	The IDS is a software-based drug-dosing calculator designed for use by the physician to calculate the next dose of any drug to achieve a desired target.	The Burn Resuscitation Decision Support System (BRDSS) is indicated for use in the care of adult patients with 20% or more Total Body Surface Area (TBSA) burned, as a fluid resuscitation calculator for hourly fluid recommendations. The BRDSS is intended to be initiated within 24 hours of the burn incident and ending by 72 hours post burn.
Intended User	Healthcare professional	Healthcare professional
Intended Use Environment	Health care facility	Hospital critical-care environment
Human Factors	Physician enters patient's glucose values and amounts of insulin. Warnings are presented when values are out of range and /or insulin doses are greater than or less than 20% of the most recent dose.	Physician or nurse enters patient weight, % of body surface area burned and time of burn. Warnings are presented when the primary fluid rate recommendation is +/- 25% (and +/- 200mL/hr) from the current primary fluid rate dose. In addition, graphs are included to show patient's cumulative volume of fluids received and hourly fluids in and urine out.
Software-Based	Yes	Yes
Dose Calculation	Yes	Yes

B. Non-Clinical Data

The BRDSS adheres to hardware requirements, such as form factor and power requirements, as well as software requirements, such as data input validation, user warnings, alerts and messages, user interface requirements, functional requirements and error handling requirements. The BRDSS includes many human factors best practices for the software user interface.

The BRDSS has passed product verification as well as clinical user validation.

Substantial Equivalence

The BRDSS and the predicate device, the TRxF Intelligent Dosing System, are both portable software-based systems that allow the healthcare professional to calculate dosages of either medicines or fluids to a patient. Both devices provide dose calculations based on relevant patient clinical data. The indications for use are very similar, and the technological and human factors features are essentially identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 18, 2013

Arcos, Incorporated
% Mr. Chris Meador
866 West 41st Street
Houston, Texas 77018

Re: K121659
Trade/Device Name: Burn Resuscitation Decision Support Software (BRDSS)
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: PDT
Dated: February 28, 2013
Received: March 04, 2013

Dear Mr. Meador:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121659

Device Name: Burn Resuscitation Decision Support System (BRDSS)

Indications for Use:

The Burn Resuscitation Decision Support System (BRDSS) is indicated for use in the care of adult patients with 20% or more Total Body Surface Area (TBSA) burned, as a fluid resuscitation calculator for hourly fluid recommendations. The BRDSS is intended to be initiated within 24 hours of the burn incident and ending by 72 hours post burn.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K121659

B. Appendix B – "Conducting a FDA Human Factors Study on a Burn Resuscitation Decision Support System" Poster

Conducting a FDA Human Factors Study on a Burn Resuscitation Decision Support System

Maria L. Serio-Melvin, RN, MSN[1], Chris Meador, MBA[2], Ada Garcia, RN[1]
United States Army Institute of Surgical Research, Fort Sam Houston, TX 78234-7767[1]
Arcos Inc., Houston, TX 77018[2]

Introduction

The FDA required a Human Factor study be conducted prior to 510 (k) clearance of the Burn Resuscitation Decision Support System-Mobile medical device. The purpose of the study was to watch for trends that showed a pattern of user failure or near-misses that were attributed to the software user interface and were of greater than minimal risk to the patient. A risk matrix on the software determined the tasks and steps that were deemed an intolerable risk to the patient. If any patterns of errors or near misses were seen, then a thorough analysis was done to determine the level of risk to the patient and mitigation strategies.

Methods

Research Determination: Non human subject research, non generalizable.

Location: Large metropolitan level I trauma center and American Burn Association accredited burn center

Participants: 30 military and civilian Registered nurses (RNs) with a minimum of two (2) years intensive care (ICU) and/or emergency department (ED) experience e study.
2 study groups: 15 RNs with burn resuscitation experience and 15 RNs without
All participants consented to being video and audio recorded.

STUDY COMPONENTS

Training:
One (1) hour PowerPoint-guided presentation
With a patient scenario, hands-on device interaction and question and answer session. There was a training delay of 1+ day(s) prior to HF study

HF Patient Simulation Testing:
- Nurses entered data into the BRDSS-M following a patient scenario.
- An observation score card was used to measure how well they entered the data.
- Referred to user manual if needed assistance

Subjective Data Question and Answer Session:
- Eight (8) interview questions were asked immediately after the simulation scenario.

User Manual (UM) Interviews:
- Half (15/30) of the participants were selected to review the user manual
- Seven (7) interview questions were asked.

Patient Simulation Scenario

Objective Score Card

Length:
2 pages
8 tasks
44 steps
~30 min

Tasks graded:
-Pass
-Poor
-Wrong
-Fail
-Fail

If other than a Pass, analysis was done.

Subjective Data Interview

Question	Response
1. What are your overall feelings about the device?	
2. Did you have any difficulty with the new patient setup (including setting time zone and system time?)	
3. Did you have any difficulty entering the checklist information?	
4. Did you have any difficulty performing the hourly fluid updates?	
5. Did you have any difficulty understanding a reading from the IO Table?	
6. Did you have any difficulty understanding the IO graphor the cumulative infusion graph?	
7. Was anything else confusing about the device?	
8. Do you have any other comments on the use of the device or what might make the device better?	

Results

We found that 3 out of 44 user-device interaction steps had more than minimal risk to the patient, were attributable to the user interface and required software changes.

Enter Patient Weight- 7/30 had difficulty or needed UM

Before

After

Enter Base Excess- All pressed the negative sign button before entering the number.

-The scenario listed a base excess of -3.5
- Negative sign did not register until a number was entered first
- Of the 30 users, 21 videos were reviewed all 21 users pressed the 'negative' sign first.

Changing Fluid Rates in Between Hourly Fluid Updates
8/30 had difficulty or higher
5/30 failed
Only 8/30 experienced nurses passed

Graphical User Interface (GUI) was not intuitive enough for nurses to know to press on the white text field.

You can change the fluid rate in both of these fields. Notice how they look different.

Software Improvements

Before

After

Task is now a line item on the user manual table of Contents and included on the Frequently Asked Questions (FAQ) section.

Conclusions

BRDSS
aka Burn Navigator

Several training, user manual and software changes were made secondary to the findings from the HF study.

A second human factor study was conducted that showed the software improvements to be effective.

We developed a valuable tool containing many user-friendly and intuitive characteristics.

Conducting a FDA Human Factors study resulted in a 510 (k) cleared medical device with an improved graphical user interface that will meet the needs of the user and ensure safety for the patient.

Conducting and participating in a HF study is surprisingly stressful.

A rare and unique set of skills are needed to properly conduct a Human Factor study on a decision support software systems designed to be used in an intensive care environment, by intensive care nurses, on critically ill patients.

BRDSS-M, renamed as Burn Navigator, is now available as a commercial-off-the-shelf medical device for military and civilian use.

Acknowledgements

Many thanks to the phenomenal nurses who gladly volunteered their time and energy to participate in this study.

References

Applying Human Factors and Usability Engineering to Optimize Medical Device Design, FDA Draft Guidance document, June 22, 1011, retrieved at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm on October 12, 2012.

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